REMARKS

I. Status of the Claims

Claims 1, 5-6, and 11-22 are pending. Support for the added limitations to claims 1 and 11 wherein the patient is required to have had prior angioplasty may be found in the specification on page 8, line 4. Support for new claims 14-17 wherein atorvastatin is administered as the sole active ingredient may be found throughout the specification, particularly on page 4, line 24 to page 5, line 2; and page 5, lines 12 – 25. Support for new claims 18 – 22 wherein the patient is defined as one who has been "referred for a recanalization procedure" may be found in the specification at page 7, lines 21 – 24. Therefore, no new matter is added.

II. Rejection Under 35 USC 112, first paragraph

Claims 1, 5 and 6 stand rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the limitation "consisting of" lacks sufficient support in the originally filed specification. Without acquiescing to the rejection, applicant has amended the transitional phrase "consisting of" to read as "comprising." Applicant respectfully submits with the amendment to the claims changing the transitional phrase "consisting of" to "comprising", this rejection is now deemed to be moot.

III. Rejection Under 35 USC 102

Claims 1, 5, 6 and 11-13 stand rejected under 35 USC 102(b) as being anticipated by Bocan, WO 97/16184. Applicant respectfully traverses this rejection.

As set forth in MPEP 2131, in order to anticipate a claim, the reference must teach every element of the claim. Bocan fails to do so.

Applicant's claimed invention is directed to a method comprising administering atorvastatin or a pharmaceutically acceptable salt thereof in an amount effective to cause an aggressive lowering of LDL cholesterol by at least forty percent from baseline or by about fifty percent or more from baseline for the prevention or delay of catheter-based revascularization in patients suffering from coronary artery disease in need of such treatment and who have undergone prior angiography.

While Bocan claims a method for regulating lipid concentration by administration of a combination of two compounds; in this instance, (a) an ACAT inhibitor and (b) a HMG-CoA reductase inhibitor (e.g. atorvastatin), applicant recognizes that there is an arm of the study on page 10 that discloses the administration of atorvastatin alone. However, Bocan is directed to a different patient population. Bocan teaches the administration of atorvastatin (mainly in combination with an ACAT inhibitor) to patients diagnosed with atherosclerosis or at risk of developing atherosclerosis. Bocan does not teach administering atorvastatin to patients who have undergone a prior angioplasty in order to prevent or delay catheter-based revascularization procedures. Prior to applicant's invention, one skilled in the art would not have concluded aggressive treatment with atorvastatin could obviate the need for surgery. Before the study disclosed in the instant application, it was not known whether aggressive treatment with cholesterol lowering drugs would be more efficacious at reducing the incidence of cardiac events as compared with treatment by catheter-based revascularization procedures. The present invention provides the basis for such a conclusion. Only 13% of patients treated with high does of a cholesterol lowering drug suffered adverse cardiac events versus 21% of patients whose blockages were cleared with a catheter-based revascularization procedure.

Patients that undergo catheter-based revascularization face risks which are different than that of patients simply being treated to lower their cholesterol. About one-third of patients who undergo surgical revascularization procedures develop restenosis, which is a re-narrowing of the surgically widened segment of the vessel. Restenosis is different from the original

stenosis (blocking of a coronary artery) that necessitated the revascularization procedure. Restenosis is a treatment-related condition (iatrogenic) associated with catheter injury to the treated vessel and subsequent proliferative cellular reocclusion of the same vessel. Restenosis is not the same as indigenous or "native" coronary atherosclerosis resulting from cholesterol accumulation in the vessel wall. The reason or mechanism fro the development of restenosis is complex and not fully understood. What is clear is that the mechanism is different than that for the formation of the original vessel blockage (stenosis). Restenosis involves the proliferation of cells including smooth muscle cells whereas stenosis is thought to involve lipid deposition and the inflammatory response. The present invention is an improvement over catheter-based revascularization in that it reduces the risk that the individual will require a surgical procedure thereby reducing the patient's risk of developing restenosis.

Therefore, considering the difference in patient population as defined in the amended claims and considering the different problem faced than the one described in Bocan, the claimed invention is clearly novel in light of Bocan.

IV. Conclusion

Applicant respectfully requests reconsideration of the subject application in view of the above amendment and remarks. The subject application is now in condition for allowance and early notice to that effect is respectfully solicited.

EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 23-0455. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,

Date: September 13, 2006

By: 

William R. Boudreaux
Attorney for Applicant
Reg. No. 35,796
(734) 622-1363

Customer No. 28880